DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 28 2010

Re: STELARA
Patent Nos. 6,902,734; 7,166,285
Docket Nos.: FDA-2010-E-0032
FDA-2010-E-0036

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,902,734 and 7,166,285, filed by Centocor Ortho Biotech Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for STELARA (ustekinumab), the human biological product claimed by the patent.

The total length of the regulatory review period for STELARA is 3,165 days. Of this time, 2,498 days occurred during the testing phase and 667 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: January 27, 2001.

   The applicant claims December 28, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 27, 2001, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: November 29, 2007.

   FDA has verified the applicant's claim that the biologics license application (BLA) for STELARA (BLA 125261/0) was initially submitted on November 29, 2007.

3. The date the application was approved: September 25, 2009.

   FDA has verified the applicant's claim that BLA 125261/0 was approved on September 25, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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